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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,093	06/18/2001	F.C. Thomas Allnutt	031676.0247	7694

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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,093

Applicant(s)

ALLNUTT ET AL.

Examiner

Deborah A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the Office Action mailed on November 4, 2004 has been acknowledged. Currently, claims 15, and 17-19 are pending and under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

3. Claim 15 remain rejected under 35 U.S.C 102 for the reasons previously set forth in the paper mailed November 4, 2004.

Applicant's arguments have not been found persuasive and the rejection is maintained.

4. Applicant argues that most phycobiliprotein linker domains would not be expected to have bilin prosthetic groups associated with them. Applicant further argues that by definition a prosthetic group cannot be a domain by itself and contends that a domain is part of a protein (polypeptide) and a prosthetic group is not a domain by itself, according to the teachings in the specification on page 8, lines 1-8, Forland's Medical dictionary and the attached appendix. This argument is noted but not found to be persuasive.

In response, although applicant contends that a bilin is not a domain by itself, the reference of Glazer et al clearly teaches that bilin is part of the phycobiliprotein domain. Also, the second domain provides a substrate for enzymes, which will naturally modify a

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corresponding natural phycobiliprotein (column 3, lines 48-66). The reference goes on to say that a wide range of displayed domains may be used including domains comprising an affinity tag, an oligomerization moiety, including polypeptides, which may be coupled to phycobiliproteins by chemical conjugation (column 3, lines 67 through column 4, lines 1-7). Therefore, according to applicant's broad definition on page 8, lines 1-8 of the instant specification, the teachings of Glazer et al phycobiliprotein domains fall within the boundaries of the limitation of claim 15.

5. Applicant argues that the current pending claims require that the fusion protein include a substrate for the enzyme, and not the enzyme itself. Applicant further directs examiner attention to the previous Office Action dated May 04, 2004, which recited luciferase as a second domain that catalyzes an enzyme. Applicant disagrees with the examiner's interpretation of the Bryan et al reference and declares that examiner has missed the point of the instant claimed invention that requires an enzyme for the substrate of a fusion protein. The examiner takes note of these arguments but they are not found to be persuasive.

In response, the claims require an enzyme for a substrate on the fusion protein. The Bryan et al reference teaches that luciferase is an enzyme that binds phycobiliproteins to convert the wavelength of light generated from the bioluminescent reaction (column 49, lines 65-67 and column 50, lines 1-5) which is a detectable change. And as pointed out in the Glazer et al reference above, phycobiliproteins may have a first or second domain that can be a substrate for an enzyme, which will

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naturally modify the phycobiliproteins. The enzyme luciferase contacts the substrate domain on the phycobiliprotein and produces a detectable change (light), which is required by the instant claimed invention. For the invention to be obvious, two things must be found in the prior art: 1) the suggestion of the invention, and 2) the expectation of its success. In re Vaek, 947 F.2d 488, 492, 20 U.S.P.Q.2d 1438, 1441 (Fed. Cir. 1991). Both references of Glazer et al and Bryan et al teach phycobiliproteins used in biological methods and therefore the examiner concludes these teachings are combinable and obvious over the instant claimed invention. Moreover, although the reference does not recite particular enzymes such as ribozyme, phosphokinase or a protease, the examiner declares that luciferase binds the substrate domain on the fusion protein and induces a detectable change, which gives this luciferase enzyme an expectation of success equal to those enzymes recited in claims of 17-19. And as stated in the previous Office Action of November 4, 2004, it would have been prima facie obvious for one of ordinary skill in the art to substitute the known enzymes of claims 17-19 in the given assay parameters to assess biological activity as a means of optimizing the assays provided by the prior art.

Conclusion

No claims are allowed.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

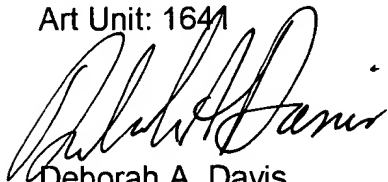
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8330.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 2, 2005



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06/24/05